

DMB

Display Date	7/21/80
Publication Date	7/24/80
Certifier	<i>[Signature]</i>

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Salinomycin and Roxarsone**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

---

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for using approved, single-ingredient salinomycin and roxarsone Type A medicated articles to make two-way combination Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, improved feed efficiency, and improved pigmentation in roaster and replacement (breeder and layer) chickens.

**DATES:** This rule is effective *[insert date of publication in the Federal Register]*.

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-135 that provides for use of approved Bio-Cox® (30 or 60 grams per pound (g/lb) of salinomycin activity) and 3-Nitro® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make combination Type C medicated feeds for use in roaster and replacement (breeder and layer) chickens. The combination Type C medicated feeds contain 40 to 60 g per ton (g/ton) salinomycin and 22.7 to 45.4 g/ton roxarsone, and they are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain, improved feed efficiency, and

cv9954

NFR 1

improved pigmentation. The NADA is approved as of May 26, 2000, and the regulation in 21 CFR 558.550 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

### **List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

2. Section 558.550 is amended by adding paragraph (d)(3)(iv) to read as follows:

**§ 558.550 Salinomycin.**

\* \* \* \*

(d) \* \* \*

(3) \* \* \*

(iv) *Amount per ton.* Salinomycin, 40 to 60 grams; and roxarsone, 22.7 to 45.4 grams.

(a) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter.

Salinomycin as provided by No. 063238 and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

\* \* \* \* \*

Dated: 7/7/00  
July 7, 2000

S F S

Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

J. N. Windsor

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F